K080640

MAR 21 2008

Exhibit B 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92(c).

The assigned 510(k) number is: _____.

1. Submitter:

Shenzhen Mindray Bio-medical Electronics Co., LTD
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

Tel: +86 755 2658 2888
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Contact Person:
Li Dongling
Shenzhen Mindray Bio-medical Electronics Co., LTD
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park,
Nanshan, Shenzhen, 518057, P. R. China

Date Prepared: January 31, 2008

2. Device Name: M5 Diagnostic Ultrasound System

Classification
Regulatory Class: II
Review Category: Tier II
21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System (90-IYN)
21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (90-IYO)
21 CFR 892.1570 Diagnostic Ultrasound Transducer (90-ITX)

3. Marketed Device:

M5 Diagnostic Ultrasound System is substantially equivalent to the following devices: Mindray DC-6 (K#072164), GE Logiq 9 (K#061129) and GE Logiq E diagnostic ultrasound system (K#072797), Mindray DP-6600 (K#060949).

4. Device Description:

The M5 is a portable general purpose, mobile, software controlled, ultrasonic diagnostic system. Its function is to acquire and display ultrasound data in B-Mode, M-Mode, PW-Mode, Color-Mode, Power-Mode, Dirpower-Mode or the combined mode (i.e. B/M-Mode).This system is a Track 3 device that employs an array of probes that include linear array and convex linear array with a frequency range of approximately 2.5 MHz to 14 MHz.

5. Intended Use:

The device is intended for use by a qualified physician for ultrasound evaluation of fetal, abdominal, pediatric, neonatal cephalic, cardiac, small parts, transvaginal, transrectal, peripheral-vascular, muscular-skeletal(conventional and superficial).

6. Safety Considerations:

The M5 Diagnostic Ultrasound System has been tested as Track 3 Device per the FDA Guidance document "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" issued September 1997. The acoustic output is measured and calculated per NEMA UD 2 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment: 2004 and NEMA UD 3 Output Display Standard. The device conforms to applicable medical device safety standards, such as IEC 60601-1, IEC 60601-1-2, IEC 60601-2-37 and ISO 10993-1.

Conclusion:

The conclusions drawn from testing of the M5 Diagnostic Ultrasound System demonstrate that the device is as safe and effective as the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 8 2008

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
c/o Robert Mosenkis
Citech
5200 Butler Pike
Plymouth Meeting, PA 19462-1298

Re: k080640
Trade/Device Name: M5 Diagnostic Ultrasound System
Regulation Number: 21 CFR 1550
Regulation Name: Ultrasonic pulsed Doppler imaging system
Regulatory Class: Class II
Product Code: IYN IYO ITX
Dated: March 4, 2008
Received: March 6, 2008

Dear Mr. Mosenkis:

This letter corrects our substantially equivalent letter of March 21, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the M5 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

3C5s
6C2s
6CV1s
7L4s
7L6s

10L4s
6LE7s
6LB7s

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Robert Phillips, Ph.D., at (240) 276-3666.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Mindray Co. Ltd.- M5 Diagnostic Ultrasound System

Diagnostic Ultrasound Indications for Use Form

System × Transducer _____

Model: M5

510(k) Number(s) _____

Clinical Application	Mode of Operation									
	A	B	M	PW D	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N		N	N		N	Note 1, 2, 3
Abdominal		N	N	N		N	N		N	Note 1, 2, 3
Intraoperative (specify)*										
Intraoperative Neurological										
Pediatric		N	N	N		N	N		N	Note 1, 2, 3
Small organ(specify)**		N	N	N		N	N		N	Note 2, 3
Neonatal Cephalic		N	N	N		N	N		N	Note 2, 3
Adult Cephalic		N	N	N		N	N		N	Note 2, 3
Cardiac		N	N	N		N	N		N	Note 2, 3
Transesophageal										
Transrectal		N	N	N		N	N		N	Note 2
Transvaginal		N	N	N		N	N		N	Note 2, 3
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N		N	Note 2, 3
Laparoscopic										
Musculo-skeletal Conventional		N	N	N		N	N		N	Note 2, 3
Musculo-skeletal Superficial		N	N	N		N	N		N	Note 2, 3
Other (specify)***		N	N	N		N	N		N	Note 2, 3

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments:Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

***Other use includes Urology/Prostate.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3: iScape

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K080640

Diagnostic Ultrasound Indications for Use Form

System ____ Transducer ×

Model: 3C5s

510(k) Number(s) _____

Clinical Application	Mode of Operation									
	A	B	M	PW D	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N		N	N		N	Note 1, 2, 3
Abdominal		N	N	N		N	N		N	Note 1, 2, 3
Intraoperative (specify)*										
Intraoperative Neurological										
Pediatric		N	N	N		N	N		N	Note 1, 2, 3
Small organ(specify)**										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Urology)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments:Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3: iScape

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Prescription USE (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K080640

Diagnostic Ultrasound Indications for Use Form

System ____ Transducer ×

Model: 6C2s

510(k) Number(s) _____

Clinical Application	Mode of Operation									
	A	B	M	PW D	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		N	N	N		N	N		N	Note 2, 3
Intraoperative (specify)*										
Intraoperative Neurological										
Pediatric		N	N	N		N	N		N	Note 2, 3
Small organ(specify)**										
Neonatal Cephalic		N	N	N		N	N		N	Note 2, 3
Adult Cephalic		N	N	N		N	N		N	Note 2, 3
Cardiac		N	N	N		N	N		N	Note 2, 3
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments:Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

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Prescription USE (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K080640

Diagnostic Ultrasound Indications for Use Form

System ____ Transducer ×

Model: 6CV1s

510(k) Number(s) _____

Clinical Application	Mode of Operation									
	A	B	M	PW D	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N		N	N		N	Note 2, 3
Abdominal										
Intraoperative (specify)*										
Intraoperative Neurological										
Pediatric										
Small organ(specify)**										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		N	N	N		N	N		N	Note 2, 3
Transvaginal		N	N	N		N	N		N	Note 2, 3
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)***		N	N	N		N	N		N	Note 2, 3

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments:Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3: iScape

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Prescription USE (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number K080640

Diagnostic Ultrasound Indications for Use Form

System ____ Transducer ×

Model: 7L4s, 7L6s, 10L4s

510(k) Number(s) _____

Clinical Application	Mode of Operation									
	A	B	M	PW D	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)*										
Intraoperative Neurological										
Pediatric										
Small organ(specify)**		N	N	N	N		N		N	Note 2, 3
Neonatal Cephalic		N	N	N	N		N		N	Note 2, 3
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N	N		N		N	Note 2, 3
Laparoscopic										
Musculo-skeletal Conventional		N	N	N	N		N		N	Note 2, 3
Musculo-skeletal Superficial		N	N	N	N		N		N	Note 2, 3
Other (specify)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments:Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3: iScape

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Prescription USE (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K080640

Diagnostic Ultrasound Indications for Use Form

System ____ Transducer X

Model: 6LE7s

510(k) Number(s) _____

Clinical Application	Mode of Operation									
	A	B	M	PW D	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N		N	N		N	Note 3
Abdominal										
Intraoperative (specify)*										
Intraoperative Neurological										
Pediatric										
Small organ(specify)**										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		N	N	N		N	N		N	Note 3
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)***		N	N	N		N	N		N	Note 3

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments:Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3: iScape

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K080640

Mindray Co. Ltd. - M5 Diagnostic Ultrasound System

Diagnostic Ultrasound Indications for Use Form

System ____ Transducer X

Model: 6LB7s

510(k) Number(s) _____

Clinical Application	Mode of Operation									
	A	B	M	PW D	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)*										
Intraoperative Neurological										
Pediatric										
Small organ(specify)**										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		N	N	N		N	N		N	Note 2,3
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)***		N	N	N		N	N		N	Note 2,3

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments:Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

***Other use includes Urology/Prostate.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

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